

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' OPPOSITION TO DEFENDANT MEDIMMUNE, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

MedImmune's individual memorandum (hereinafter "Med. MTD") seeks the dismissal of all claims on the grounds that plaintiffs have failed to state a claim against it and have not satisfied Fed. R. Civ. P. 9(b). MedImmune's motion should be denied. Plaintiffs have satisfied Fed. R. Civ. P. 9(b) and this Court's prior rulings¹ as detailed below.

Plaintiffs allege that MedImmune reported, or caused to be reported, fraudulent wholesale pricing information that resulted in fraudulent AWP's and WAC's. In fact, MedImmune's has admitted that its AWP's are inflated to cover administration costs. *See infra* at n.6. Plaintiffs further allege fraudulent WAC's and AWP's for all MedImmune drugs for which they seek relief and properly use generally available market prices to demonstrate MedImmune actionable spreads as instructed by this Court in *Suffolk II*.² This specificity satisfies the particularity requirements of Fed. R. Civ. P. 9(b) and this Court's prior rulings, including all those in *Suffolk*. Furthermore, the Court did not dismiss all claims against MedImmune in *Suffolk*, as explained below. For the aforementioned reasons, MedImmune's motion must be denied.³

DISCUSSION

A. Plaintiffs' AWP Claims Are Pled With Sufficient Particularity

In order to maintain AWP Claims, plaintiffs must set forth factual allegations regarding

¹ See *In re Pharm. Indus. Average Wholesale Price Litig.* 339 F.Supp.2d 165, 173 ("*Suffolk I*"); *In re Pharm. Indus. Average Wholesale Price Litig.*, 2004 WL 2387125, at *3 (D. Mass., Oct. 26, 2004) ("*Suffolk II*"); *In re Pharm. Indus. Average Wholesale Price Litig.* Memorandum and Order at 1-2 (D. Mass., April 8, 2005) ("*Suffolk III*")

² See Corrected Consolidated Complaint, filed on June 22, 2005 ("Consolidated Complaint" or "CC") at ¶¶ 589-595, CC Exh. A & B; Nassau Second Amended Complaint, filed on January 6, 2006 ("Nassau SAC" or "NSAC") at ¶¶ 489-496, NSAC Exh. A & B

³ All other causes are addressed in Plaintiffs Consolidated Opposition to Defendants Motion to Dismiss, filed contemporaneously herewith (referred to herein as "Consolidated MTD Opposition").

spread, internal documents or government investigations from which an inference of fraud can reasonably be made. *See Suffolk II*, 2004 WL 2387125 at *2; *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 209 (D. Mass. 2004) (“*Pharm. III*”) (recognizing an industry-wide practice of inflating AWP’s and not requiring a specific spread for every drug of each manufacturer). In addition, the Court has required plaintiffs to allege a spread that does not rely on averaging. *See Suffolk III*, at 2.

Plaintiffs (1) provide fraudulent AWP’s for Respigam, Cytogam and Synagis, products for which plaintiffs paid (*see* CC Exh. A at 50; *see* NSAC Exh. B at 41); (2) detail spreads calculated based on actual available market prices⁴ -- not an industry average price -- for Cytogam⁵ (*see* CC Exh. B at 20; NSAC Exh. A at 29); (3) allege that MedImmune admitted that it inflated its AWP to reimburse physician administering costs;⁶ (4) allege that MedImmune, like all defendants here, set its false AWP’s by either directly supplying the false AWP’s to publishers or supplying false WAC or WAC equivalents to the publishers (CC ¶6; NSAC ¶ 5); and (5) allege that the MedImmune’s WAC itself is false and inflated and that MedImmune knows that by reporting a false and inflated WAC or WAC equivalent they can trigger the publications of the false and inflated AWP on which

⁴ Plaintiffs spreads are based on actual wholesale prices available to to Ven-a-Care of the Florida Keys, Inc. (“Ven-a-Care”), a licensed pharmacy, and other independent pharmacies participating in the ServAll program. These prices, substantially below reported AWP’s, demonstrate the inflated nature of AWP’s. In the matter styled, *State of California ex rel. Ven-a-Care of the Florida Keys v. Abbott Labs., et al.*, also pending before this Court, the California AG utilized these same prices to calculate the spreads in support of similar claims. The legitimacy of these prices was not questioned by any defendant in motions to dismiss filed in that action. Plaintiffs informed the Court and all defendants, including MedImmune, the source of plaintiffs’ pricing data. *See* Plaintiffs’ Response to Defendants’ Request for Extension of Time and Further Relief in Order to comply with July 8, 2005 Order (filed October 12, 2005).

⁵ The spread for MedImmune’s Cytogam (Exhibit B to CC) is sufficient to infer a fraud to Respigam and Synagis. *See Pharm III*, 307 F. Supp. 2d 196, at 209 (rejecting the argument that plaintiffs’ must allege a specific spread for each drug, so long as specific spreads were alleged on other drugs manufactured by that defendant).

⁶ Plaintiffs allege that MedImmune stated that “a physician administering Synagis encounters costs of administration which Synagis AWP is used to cover.” CC ¶592.

reimbursements are made (*see* CC ¶8; NSAC ¶6).⁷ Plaintiffs also allege that MedImmune engages in off-invoice pricing that allows a manufacturer to lower the net cost to the purchaser while concealing the actual cost beneath the fiction of a higher invoice. *See* CC ¶ 153; NSAC ¶ 159.

The foregoing is sufficient to draw a reasonable inference of a company-wide AWP Fraud in compliance with the requirements of Rule 9(b). *See U.S. ex rel Franklin v. Parke Davis*, 147 F.Supp.2d 39, 49 (D.Mass 2001) (Saris, J.) (“[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.”).

B. Plaintiffs’ Best Price Claims Against MedImmune Should Be Sustained.

In order to maintain Best Price claims, plaintiffs must “set forth minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices.” *Suffolk II*, 2004 WL 2387125, at *3.

Plaintiffs have done this. First, plaintiffs allege the name of every MedImmune drug for which they assert Best Price claims. *See* CC Exh. A & B; NSAC Exh. A & B. Second, plaintiffs allege a company-wide scheme and strategy whereby MedImmune utilized off-invoice pricing to lower prices, provide incentive to purchasers and maximize sales. Plaintiffs also allege that since 1998 MedImmune jointly promoted Synagis with Abbott’s Ross Products Unit. The Ross Products Unit caused Abbott to pay \$622 million to resolve allegations that Ross defrauded Medicaid by failing to report Best Price. *See* CC ¶¶ 196-97, 595; NSAC ¶¶ 204, 495.

⁷MedImmune contends that plaintiffs did not allege the meaning of WAC nor allege that MedImmune made a representation that WAC and AWP have a particular definition. Med. MTD at 2. But plaintiffs allege that WAC is wholesale acquisition cost. *See* CC at ¶ 5. The Court has ruled in a related case that for the purposes of a motion to dismiss WAC was understood in the industry, until at least 2002, “to mean a true price, and Defendants were misrepresenting their true prices to the Government.” *Massachusetts v. Mylan Laboratories, et al.*, 357 F.Supp.2d 314, 320-322 (D. Mass. 2005). Plaintiffs allege that, in fact, WAC was not a real price in many cases but was manipulated by defendants, including Medimmune. *See* CC at ¶¶ 8-12.

C. Plaintiffs Claims Apply to All Physician Administered Drugs

MedImmune contends that all claims for physician-administered drugs (“PADs”) should be dismissed because under New York law “when the administering physician bills directly and seeks Medicaid reimbursements, such reimbursement is based on ‘actual cost.’” Med. MTD at 3.

Plaintiffs assert their claims against MedImmune “from 1992 to the present.” CC ¶1; NSAC ¶1. New York did not begin reimbursing PADs based on actual cost until it amended the Medicaid reimbursement scheme on June 9, 1994. *See* N.Y. Soc. Serv. L. § 367-a(9)(a) (1994 amendments). Prior to June 9, 1994, New York reimbursed PADs based on fraudulent AWP. As such, all fraud-based claims between 1992 and June 9, 1994 must be sustained. Additionally, irrespective of the amendment, to the extent PADs can also be self-administered, they are reimbursed based on fraudulent AWP and plaintiffs’ theory of fraud and injury applies. Currently, there is no record before the Court that can be used to determine which MedImmune’s PADs are also self-administered and therefore reimbursed based on fraudulent AWP. Thus, the claims should be sustained until the record is developed and presented to the trier of fact.

In addition, the settlement between the State of New York and TAP regarding the marketing, sale and pricing of Lupron (the “2001 Lupron Settlement”) calls into question whether physicians in New York are, in fact, reimbursed based on “actual cost” or AWP. In the context of the 2001 settlement, the State of New York alleged that (despite the New York State statute mandating that PADs are reimbursed at acquisition cost) Lupron’s reimbursement was based on TAP’s reported AWP. NY further alleged that TAP falsely advised providers that their actual acquisition costs should not be reported to Medicaid as the basis for reimbursement. Rather, TAP counseled physicians that Lupron’s reimbursement claim for should be submitted at the inflated AWP. *See* New York State Settlement Agreement, attached as Exhibit A to Tap’s Individual

Motion to Dismiss, at II(A) (iii) at pg 3. This too presents a question for the trier of fact, not appropriately resolved at this stage of the case.

D. The Court Previously Sustained Certain Suffolk Claims Against MedImmune.

MedImmune claims “the Court dismissed all of claims of Suffolk County against MedImmune.” Med. MTD at 1. This is not correct. *See* Consolidated MTD Opposition at Procedural History Section. The Court’s *Suffolk III* decision -- regarding whether Suffolk satisfied 9(b) with respect to the “Suffolk 13 +6” -- in no way modified either its *Suffolk I* or *Suffolk II* decisions. There, the Court sustained Suffolk’s AWP-based and Best Price-based unjust enrichment claims and claims for violation of 18 N.Y.C.R.R. §515.2(b)(4) & (5) against the Suffolk 13 +6. In *Suffolk II*, the Court expressly held that Rule 9(b) did not apply to these claims, as they “do not require a pleading of fraud or mistake.” *Suffolk II*, 2004 WL 2387125 at *2.

CONCLUSION

For all the foregoing reasons, MedImmune’s Motion to Dismiss should be denied in its entirety.

Dated: April 17, 2006

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

KIRBY McINERNEY & SQUIRE, LLP
830 Third Avenue
New York, New York 10022
(212) 371-6600

/s/ Joanne M. Cicala
Joanne M. Cicala (JC 5032)
James P. Carroll Jr. (JPC 8348)
Aaron D. Hovan (AH 3290)
David E. Kovel (DK 4760) (*pro hac vice*
application pending)

For the City of New York

MICHAEL A. CARDOZO
Corporation Counsel of the
City of New York

John R. Low-Beer (JL 3755)
Richard J. Costa (RC 7278)
Assistant Corporation Counsels
100 Church Street, Room 3-162
New York, New York 10007
(212) 788-1007

LORNA B. GOODMAN

Peter J. Clines
Rachel S. Paster
Nassau County Attorney, by

MOULTON & GANS, P.C.

/s/ Nancy Freeman Gans
Nancy Freeman Gans, BBO # 184540

55 Cleveland Road
Wellesley, MA 02481
Telephone: (781) 235-2246
Facsimile: (781) 239-0353

**MILBERG WEISS BERSHAD
& SCHULMAN LLP**

Melvyn I. Weiss
Michael M. Buchman
Ryan G. Kriger
One Pennsylvania Plaza
New York, New York 10119-0165
Telephone: (212) 594-5300
Facsimile: (212) 868-1229

*Special Counsel for the
County of Nassau*